UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,625	03/08/2004	Bing-Nan Zhou	10209.575	2820

7590 07/13/2006

KIRTON & McCONKIE
Suite 1800
60 East South Temple
Salt Lake City, UT 84111

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,625	ZHOU ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-27* is/are pending in the application.

4a) Of the above claim(s) *6-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 and 4-27 are pending in the application; claims 2-3 being newly cancelled and claims 25-27 being added in the most recent amendment filed 4/25/06.

Claims 6-24 were withdrawn from the merits as being directed toward a non-elected invention. Claims 25-27 are directed toward the elected invention.

Claims 1, 4-5 and 25-27 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'eliminating the alcohol and alcohol-soluble ingredients". This phrase is ambiguous in that it appears that Applicant is claiming that the extract is devoid of alcohol-soluble ingredients which is in direct conflict with what is actually

taught in the Specification. This language causes confusion because the metes and bounds of what Applicant intends to claim is unclear. Because claims 4 and 5 depend upon claim 1, and do not remedy the indefiniteness of claim 1, claims 4 and 5 necessarily possess all of the claim limitations of claim 1 and are thus also found indefinite.

Claim 25 recites 'removing all liquids from said crushed dry leaves to obtain a leaf extract'. This statement is ambiguous in that it appears that Applicant is claiming that the dry leaves *is* the extract. Again, it appears that Applicant intends for the leaves to be an extract which is incorrect in the context of the meaning of the word 'extract'. The Specification teaches that what is actually combined with the fruit juice of *Morinda citrifolia* is an ethanolic extract of *Morinda citrifolia* leaves, whereby the ethanol has been removed from the extract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-5 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinicke (US 4,666,606).

Heinicke (US 4,666,606) taught a composition high in xeronine and/or proxeronase/proxeroninase content comprising *Morinda citrifolia* juice (aka noni juice) which was processed from thawed green noni fruits – col.6, lines 48-64. Heinicke specifically stated that 'Special efforts can be made to increase the xeronine content of the percolate fraction by adding a source of proxeroninase. It has been found that Noni leaf extract or whey may be added to the juice' (col.5, lines 55-58). Heinicke further specifically suggested an extract of whey to be added to the composition (col.5, lines 55-58). The term 'carrier' is given it's broadest interpretation within reason lacking any specific definition of the term 'carrier' within the Instant specification. Therefore, whey extract is considered a 'carrier'.

It has been newly found in the Heinicke patent that proxeronine was known to be an alcohol-soluble protein: "Proxeroninase was first isolated from milk in the forties as an alcohol soluble protein" (col.2, lines 39-40).

Heinicke did not specifically teach wherein the noni leaves were crushed and dry, or wherein all of the liquid had been removed.

One of ordinary skill in the art would have been motivated to obtain an extract from dry, crushed noni leaves, as dry noni leaves are essentially devoid of water and therefore easily stored to retain active ingredients therein. One of ordinary skill in the art would have been motivated to extract leaves which have been crushed because plant matter which has been crushed, or essentially comminuted, provides a larger surface area for extraction thereby increasing yield of solvent-soluble material. One of ordinary skill in the art would have been motivated to remove all liquid after extraction of the leaf in order to remove unwanted liquid such as non-edible alcohol (e.g., ethanol, methanol) and to concentrate the active components of the noni leaf. Further, it was clear that proxeroninase was alcohol-soluble. Thus, one of ordinary skill in the art would have had a reasonable expectation that the extract of leaves to which Heinicke proposed as an enrichment factor to *Morinda citrifolia* juice was the alcoholic extract.

Applicant's arguments were fully considered. Applicant argues that because claim 2 has been incorporated into claim 1, and because the Examiner indicated that claim 2 was free of the art, that the claim 1 is allowable. This is not found persuasive and is moot in light of the newly found teaching of Heinicke. Further, Applicant has not overcome the 112 Second paragraph rejections because it remains unclear exactly what the extract being claimed is (see rejection under 35 USC 112 Second paragraph *supra*).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

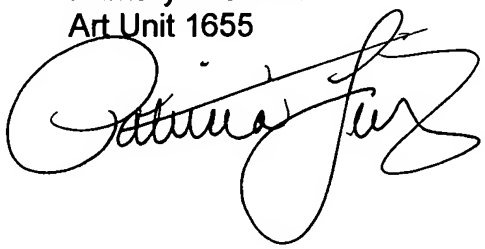
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655



June 30, 2006